

REMARKS

In the Office Action dated April 24, 2002, the Patent Office required the restriction to one of the following inventions: Group I, Claims 1-11 and 15-20, drawn to an introducing device and method of use; and Group II, Claims 12-14, drawn to a catheter. The Patent Office stated that the inventions are distinct from each other because the apparatus of Group I and the apparatus of Group II may be used separately in other combinations or completely separately. More specifically, the Patent Office alleges the introducer device of Group I may be used to hold any tube, flexible or non-flexible, or needle; it may be used for biopsies, suturing, procedures. Further, the Patent Office alleges the catheter of Group II may be utilized for epidural in the field of anesthesia, by placing it in another catheter with a hard shell and a balloon and may be used as a drug delivery device, for aspiration of body fluids or for monitoring of body fluids. Further, the Patent Office made no objections or rejections to any of the claims.

By the present Amendment, Applicant amended Claims 1-11 and 15-20. Applicant submits that the amendments to the claims overcome the restriction requirement by the Patent Office for the reasons that follow.

Claims 1-11 and 15-20 where amended to include the specific structure of the catheter of Claims 12-14. Applicant submits that the introducing device of Claims 1-11 and 15-20 is designed for the structure of the catheter claimed in Claims 12-14 of the present application. Accordingly, the structure of the catheter defined in Claims 12-14 has been incorporated into independent Claims 1, 7, and 15. Applicant submits that the claims, as amended, of Group I and Group II, do NOT define two distinct inventions and respectfully request that the restriction requirement be withdrawn. Notice to that effect is requested.



As to the assertion made by the Patent Office that the introducer device of Group I may be used to hold any tube, flexible or non-flexible, or needle, Applicant submits that the introducer may be used to hold only the flexible hollow body required by the claims.

By the present response to the restriction requirement, Applicant elects herewith, with traverse, the claims of Group II, namely Claims 12-14. Nonetheless, Applicant submits that all claims, Claims 1-20, should now be examined since Applicant incorporated the structure of the catheter into independent Claims 1, 7 and 15 and dependent Claims 16-20. Accordingly, all claims of the application should now be examined.

In view of the foregoing remarks and amendments, Applicant respectfully submits that all of the claims in the application are in allowable form and respectfully solicits allowance of the same. If, however, any outstanding issues "remain, Applicant urges the Patent Office to telephone Applicant's attorney so that the same may be resolved and the application expedited to issue. Applicant requests the Patent Office to indicate all claims as allowable and to pass the application to issue.

Respectfully submitted,

/(Reg. No. 35,018

Brian M. Mattson

Patents + TMS

A Professional Corporation

1914 N. Milwaukee Ave.

Chicago, Illinois 60647 Telephone: (773) 772-6009

Attorney for Applicant

CERTIFICATE OF MAILING

I hereby certify that this Response to Restriction Requirement and Amendment is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Asst. Commissioner for Patents, Washington, D.C. 20231 on May 23, 2002.

Brian M. Mattson (Reg (No. 35,018)

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VERSION WITH MARKS TO SHOW CHANGES MADE

IN THE CLAIMS:

Please amend Claim 1 as follows:

- 1. A catheter (introducing device) for placing [a catheter] within a body, the catheter [introducing device] comprising:
- a flexible hollow body defining a length between a top end and a bottom end wherein the top end is closed and wherein the top end tapers to a cylindrical tube;
 - a diameter defined by the cylindrical tube;
- a width defined by the bottom end of the flexible body wherein the width is greater than the diameter;
- a locking mechanism located on the bottom end of the flexible body;
- a first notch located a distance from a point at which the top end meets the cylindrical tube; and
 - a second notch located a distance from the bottom end;
- a cylindrical body defining a cross with a length defined between a pointed end and a flat end;
- a first part having a uniform width and a length defined between the pointed end and the flat end; [and]
- a second part defining a cross with a length defined between a pointed end and a flat end wherein the first part and the second part define the cylindrical body and further wherein the top end of the flexible hollow body is removably attached to the second part of the cylindrical body.

Please amend Claim 2 as follows:

- 2. The [device] catheter of Claim 1 further comprising:
- a locking mechanism located at the flat end of the cylindrical body wherein the first part and the removable second part are locked together.



Please amend Claim 3 as follows:

- 3. The [device] catheter of Claim 1 further comprising:
- a cylindrical portion wherein the pointed end of the cylindrical body gradually tapers to the cylindrical portion.

Please amend Claim 4 as follows:

4. The [device] <u>catheter</u> of Claim 1 wherein the cylindrical body has sufficient structural strength to penetrate through skin and into a subcutaneous layer of a body.

Please <u>amend</u> Claim 5 as follows:

- 5. The [device] catheter of Claim 1 further comprising:
 - a recessed portion along the length of the first part; and
- a protruding element defined in shape by a right angle located along the recessed portion of the first part.

Please amend Claim 6 as follows:

- 6. The [device] catheter of Claim 1 further comprising:
- a protrusion along the length of the removable second part of the cylindrical body wherein the recessed portion along the length of the first part may readily accept the protrusion along the length of the removable second part.

Please amend Claim 7 as follows:

- 7. A catheter [introducing device] for placing [a catheter] within a body, the catheter [introducing device] comprising:
- a flexible hollow body defining a length between a top end and a bottom end wherein the top end is closed and wherein the top end tapers to a cylindrical tube;
 - a diameter defined by the cylindrical tube;
- a width defined by the bottom end of the flexible body wherein the width is greater than the diameter:

- a locking mechanism located on the bottom end of the flexible body;
- a first notch located a distance from a point at which the top end meets the cylindrical tube;
 - a second notch located a distance from the bottom end;
- a cylinder having a length defined between a pointed end and a [bottom] second end wherein the top end of the flexible hollow body is removably attached to the pointed end of the cylinder;
- a first hole located a distance from the pointed end of the cylinder;
 - a leg attached to the bottom end of the cylinder;
 - a second hole located on the leg of the cylinder; and
- a thread connected to the cylinder from the second hole to the first hole.

Please amend Claim 8 as follows:

- 8. The [device] catheter of Claim 7 further comprising:
- a groove cut into the cylinder having a length defined between the first hole and the pointed end.

Please amend Claim 9 as follows:

- 9. The [device] catheter of Claim 7 further comprising:
 - a locking mechanism located on the leg of the cylindrical body.

Please amend Claim 10 as follows:

- 10. The [device] <u>catheter</u> of Claim 7 further comprising:
- a cylindrical portion wherein the pointed end of the cylinder gradually tapers to the cylindrical portion.

Please amend Claim 11 as follows:

11. The [device] <u>catheter</u> of Claim 7 wherein the cylinder has sufficient structural strength to penetrate through skin and into a subcutaneous layer of a body.

Please amend Claim 15 as follows:

15. (Twice amended) A method for introducing a catheter into a body of a patient wherein the body includes skin and a subcutaneous layer, the method comprising the steps of:

providing a flexible hollow body defining a length between a top end and a bottom end and having a notch located a distance from the top end;

providing a second notch located a distance from the bottom end:

providing a first part having a length defined between a pointed end and a flat end;

providing a second part having a length defined between the pointed end and the flat end wherein the first part and the second part define a cylindrical body and further wherein the second part is removable;

providing a locking mechanism located at the flat end of the cylindrical body wherein the first part and the second part are locked together;

piercing the skin and the subcutaneous layer of the body with the pointed end of the cylindrical body;

pushing the cylindrical body through the subcutaneous layer wherein the cylindrical body is exposed outside an exit site of the body;

removing the second part of the cylindrical body;

attaching [a catheter] the notch of the flexible hollow body to the first part of the cylindrical body;

pulling the first part of the cylindrical body and the [catheter] <u>flexible hollow body</u> into the subcutaneous layer and the entry site; and

removing the first part of the cylindrical body from the [catheter] <u>flexible hollow body</u> and pulling the [catheter] <u>flexible hollow body</u> into the subcutaneous layer.

Please amend Claim 16 as follows:

16. The method of Claim 15 further comprising the step of: preventing the [catheter] <u>flexible hollow body</u> from slipping.

Please amend Claim 17 as follows:

17. The method of Claim 15 further comprising the step of: suturing the (catheter) <u>flexible hollow body</u> to the skin of the body.

Please amend Claim 18 as follows:

18. (Twice Amended) The method of Claim 15 further comprising the step of:

attaching the [catheter] <u>flexible hollow body</u> to the first part of the cylindrical body by placing the [catheter] <u>top end of the flexible hollow body</u> on the first part of the cylindrical body.

Please amend Claim 19 as follows:

19. (Twice Amended) The method of Claim 15 further comprising the step of:

securing the [catheter] <u>flexible hollow body</u> to the first part of the cylindrical body with a thread.

Please amend Claim 20 as follows:

20. (Twice Amended) The method of Claim 15 further comprising the step of:

securing the [catheter] <u>flexible hollow body</u> to the first part of the cylindrical body by fitting the [catheter] <u>flexible hollow body</u> to a notch on the first part of the cylindrical body.